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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

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Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6006

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

January 3, 2000

WARNING LETTER

Mr. John Warehime
President
Hanover Foods
1550 York Street, Rt. 116E
Hanover, Pa 17331

FILE NO: 00-NWJ-18

Dear Mr. Warehime:

We inspected your firm, Sunnyside Fresh Foods Inc. located at 730 Lebanon Road, Millville, NJ 08332 on June 4, 8, and found that you have serious deviations from the Seafood HACCP regulations (Title 21 of the Code of Federal Regulations (CFR) Part 123). These deviations, some of which were previously brought to your attention, cause your seafood salad to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. You must take an appropriate corrective action when a deviation from a critical limit occurs, in order to comply with 21 CFR 123.7(a). However your firm did not take an appropriate corrective action to control the hazard of bacterial pathogens when your process for seafood salad deviated from your critical limit at the Refrigerated Storage Critical Control Point. Records indicate that one of your refrigerated storage trailers (#322852) exceeded the critical limit of [redacted] degrees Fahrenheit and you failed to take the corrective action listed in your plan (microbiological analysis) prior to product release.

2. Your HACCP plan for Seafood Salad is not adequate in that your refrigerated trailers are not included in the monitoring section under your Critical Control Point, Refrigerated Storage. [21 CFR 123.6(c)(4)].

3. Your HACCP plan for your Seafood Salads, does not address the Clostridium botulinum hazard for MAP (modified atmosphere packaged) surimi [21 CFR 123.6(c)(1)]. We recognize that you have correctly identified Refrigerated Storage as a Critical Control Point (CCP); however the critical limit for temperature at [redacted] degrees Fahrenheit will not prevent the growth of non-proteolytic Clostridium botulinum.

4. You must adequately monitor sanitation conditions and practices during processing, in order to comply with 21 CFR 123.11(b). However, your firm failed to monitor the protection of food from adulteration, the condition and cleanliness of food contact surfaces, and the prevention of cross contamination from insanitary objects. Water, splashed up from puddles on the floor, was seen hitting staged tuna only partially covered by a tarp. Employees rinsed their hands in hand-dip stations, which contained no detectable level of chlorine in them, and then handled ready-to-eat seafood salads.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

We acknowledge receipt of your response dated June 23, 1999. The hazard of Clostridium botulinum needs to be addressed in your HAACP plan. Your current critical limit of [redacted] degrees Fahrenheit will not prevent growth of non-proteolytic Clostridium botulinum. Please respond with a discussion of your corrective action to the issue discussed in this paragraph as well as the issues discussed in this letter within three weeks from your receipt of this letter. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your written reply should be directed to the Food and Drug Administration, Attention: Diane B. Radice, Compliance Officer, FDA, 10 Waterview Blvd., Parsippany, NJ 07054, telephone (973) 526-6006.

Sincerely,

Douglas I. Ellsworth

DOUGLAS I. ELLSWORTH
DISTRICT DIRECTOR
NWJ-DO